## REMARKS

Status of the claims

Claims 1-2, 4-6, 8, 14-19, 21-26, 28, 34-37, 43-44, 50 and 51are pending and rejected herein. No new matter is added.

The 35 U.S.C. § 103(a) Rejection

Claims 1, 2, 4-6, 8, 13-19, 21-26 and 28 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Bernaz** (WO 02/053046, US pub. No. 2004/0092956, English version) in view of **Sage,** Jr. et al (US Pub. No. 2003/0199811A1) and further in view of Tapper (U.S. Patent No. 6,235,013). Applicants respectfully traverse this rejection.

The examiner states that **Bernaz** discloses a device for altering or ablating tissue comprising an actuator having an inferior surface adapted to contact an abrasive member contacting abrasive material deliverable onto a tissue, a means to drive the actuator at high frequency, a container formed by ridges capable of holding pharmaceuticals until delivery by mechanical pressure operably connected distally to the device having an opening there through adapted to deliver an abrasive material therein to the tissue, a lubricant comprising water (PPs 0019, 0025-0029, 0031-0032, 0046-0047, 0052, 0055, and 0062-0063). The Examiner also states that **Bernaz**'s device is capable of use with various tissues and pharmaceuticals. The Examiner states further that Bernaz does not explicitly disclose the use of a separate container for the pharmaceutical, but that Sage Jr. reference teaches the use of pharmaceutical reservoir in a skin abrasion device for delivering a pharmaceutical. Hence, the Examiner states, it would be obvious to one of ordinary skills in the art, to incorporate the reservoir of Sage into the device of Bernaz to allow for the delivery of pharmaceutical for different medical treatments. The Examiner further states, that although Bernaz in view of Sage Jr. does not teach permeable membrane adapted to controllably release said pharmaceutical, Tapper et al do. Tapper teaches the use of a membrane for a pharmaceutical container (18a & 18b in Figs. 2-3). The Examiner concludes it would have been obvious for one of ordinary skill in the art to modify the device of Bernaz with the teachings of Tapper to provide a convenient container for quick access to the desired substance and efficiency.

**Bernaz** et al teach a device for cosmetic skin dermabrasion that has a curved U-shaped abrasive surface, held by a support mounted in a housing, which is driven to oscillate about its axis to effect the abrasion of the epidermis (Abstract). Alternatively, the device comprises a support piece with a double reversible face, including the curved abrasive surface and on the other side a surface equipped with striations designed for a massage treatment.

**Sage** Jr. et al teach a device that includes a plurality of microneedles for abrading the stratum corneum of the skin to form a plurality of grooves in the tissue having a controlled depth and width. The microneedles have a length of about 5-250 microns and generally about 5-200 microns. The device is rubbed over the skin to prepare an abraded site after which a transdermal delivery or sampling device is applied to the abraded delivery site. The abrasion increases the permeability of the skin and the rate of delivery and extraction of a substance without pain or irritation to the patient.

**Tapper** teaches an iontophoretic treatment system where the electrical current between a pair of electrodes is periodically reversed at low frequencies during an iontophoretic procedure to deliver treatment substances (Abstract). The device comprises two semicircular electrode chambers including a gel containing a drug or felt pads containing the drug therein.

**Bernaz** et al neither teach or suggest the claim element of an ablative device including an operably connected means to deliver a pharmaceutical to a tissue during ablation thereof. **Bernaz** specifically teaches that any treating compound is applied to the ablated epidermis after treatment and requires the application of electromagnetic radiation to cause permeation of the compound [0032]. **Bernaz** et al teach cosmetic skin dermabrasion. Microdermabrasion involves removal of the surface on the outer part of the skin completely or almost completely, by a source of abrasion by light. The particles left behind afterwards are then removed by being vacuumed through a small wand like instrument. Microdermabrasion benefits are the reduction and erasing of damage from the sun, reduction in the size of the skin pores, reduction in the appearance of fine lines, sun spots and wrinkles. It is not the objective of dermabrasion to deliver pharmaceuticals as is taught by the instant invention. Moreover, dermabrasion is not intended to, nor capable of, complete removal of the stratum corneum. This is an important distinction, and enables maximum penetration of a compound.

Hence, one of ordinary skills in the art would lack the motivation to combine the teachings of **Sage** Jr. that specifically teach the use of pharmaceutical reservoir in a skin abrasion

device for delivering a pharmaceutical with **Bernaz** et al to arrive at the instant invention. Although, both Bernaz et al and Sage Jr. et al teach ablation of the stratum corneum, the purpose of this ablation as taught by Bernaz et al is to achieve purely cosmetic results. On the contrary, Sage et al mediate the abrasion to increase the permeability of the skin in order to increase the rate of delivery or extraction of a substance without pain or discomfort to the patient. Further, one would, for the same reason, lack a motivation to combine the teachings of **Tapper** et al, that teaches the use of a membrane as a pharmaceutical container, to arrive at the instant invention.

Applicants reassert that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching, suggestion, or incentive supporting the combination. Applicants aver that no such suggestion or incentive may be gleaned from the references relied upon by the Examiner. Accordingly, in view of the arguments presented supra, Applicants respectfully request that the rejection of the claims 1, 2, 4-6, 8, 13-19, 21-26 and 28 rejected under 35 U.S.C. § 103(a) be withdrawn.

Claims 34-37 and 50-51 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bernaz et al (WO 02/053046, US pub. No. 2004/0092956) in view of **Sage,** Jr. et al (US Pub. No. 2003/0199811A1), in view of **Tapper** (U.S. Patent No. 6,235,013 B1) and in view of **Eggers** (U.S. Patent No. 6066134). Applicants respectfully traverse this rejection.

The Examiner states that **Bernaz** in view of **Sage** Jr. and **Tapper** discloses the claimed invention except for monitoring feedback using electrical property of the tissue with the device. The Examiner states that this deficiency is overcome by the teachings of **Eggers** et al, hence it would have been obvious to one of ordinary skills in the art to use the teachings of Eggers in the device of **Bernaz** to increase the safety of the ablation procedure for better patient outcome.

**Bernaz**, **Sage** Jr., and **Tappers** et al are discussed supra. **Eggers** et al teach an electrosurgical probe comprising a shaft having an electrode array, as active electrode, at its distal end, a return electrode recessed within a shaft and a connector at its proximal end for coupling the electrode array to a high frequency power. Eggers et al teach thermal monitoring of the surface of the electrode array to regulate current flow.

A combination of **Bernaz**, **Sage** Jr., and **Tapper** fails to teach the claim element of an ablative device including an operably connected means to deliver pharmaceutical to a

tissue during ablation thereof as discussed supra. Combining **Eggers** with **Bernaz** would not remedy this deficiency. Therefore claim 1 is non-obvious over **Bernaz** et al in view of **Eggers** et al. Claims 34-37 and 50-51 depend directly or indirectly from claim 1. Therefore, claims 34-37 and 50-51 are also non-obvious over **Bernaz** et al in view of **Eggers** et al.

Claims 43-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bernaz et al (WO 02/053046, US pub. No. 2004/0092956) in view of **Sage,** Jr. et al (US Pub. No. 2003/0199811A1), in view of **Tapper** (U.S. Patent No. 6,235,013 B1) and further in view of Weaver et al (US Pub. No. 2002/0065533A1). Applicants respectfully traverse this rejection.

Examiner states that a combination of Bernaz with Sage Jr., and Tapper discloses the claimed invention except for a controlled means to monitor fluorescence or reflectance of the tissue comprising a radiant source, detector and a controller. Weaver et al teaches a radiant energy source, light detector and controller capable of monitoring a change in optical property of the tissue. Hence, the Examiner contends, it would have been obvious to one of ordinary skills in the art to combine the teaching of Weaver et al with Bernaz to increase the safety of the ablation procedure for better patient outcome.

Applicants submit that as discussed supra, the instant invention is not rendered obvious over a the combined teachings of **Bernaz, Sage** Jr., and **Tapper** et al. **Weaver** et al teach an apparatus that creates microconduits by impinging the skin using a plurality of accelerated microparticles possessing enough velocity to cut the skin for localized delivery of molecular and ionic transport to/from tissue via the created microconduits. **Weaver** et al teach penetration of the epidermis and the dermis. The monitoring means in Weaver et al uses a reflecting means to determine that the microconduit has first reached a capillary bed by measuring change in reflectance due to the initial appearance of blood. This allows for the safe measurement of an analyte in the blood within the microconduit.

**Bernaz** et al teach cosmetic microdermabrasion and do not teach complete removal of the epidermis or penetration of the dermis. The epidermis does not contain any capillary bed hence reflectance monitoring as taught by Weaver et al would not be applicable to **Bernaz** et al. Thus since a combination of **Bernaz, Sage** Jr. and **Tapper** does not render the instant invention obvious and further Weaver also does not remedy this deficiency, claims 43-44 which also depend directly or indirectly from claim 1 are not rendered obvious. Accordingly, in

view of the arguments presented supra, Applicants respectfully request that the rejection of claims 43-44 under 35 U.S.C. § 103(a) be withdrawn.

This is intended to be a complete response to the Office Action, mailed February 22, 2007. Applicants submit that pending claims 1-2, 4-6, 8, 14-19, 21-26, 28, 34-37, 43-44, 50 and 51 are in condition for allowance. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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